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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. AKORN, INC., Defendant.	)	Civil Action No. 13-XXXX (XXX) (XXX)

COMPLAINT

1. Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") alleges as follows on personal knowledge as to its own actions and observations, and on information and belief as to all other facts.

NATURE OF THE ACTION

2. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 that arises out of Defendant's requests for approval from the U.S. Food and Drug Administration ("FDA") to manufacture and sell generic versions of Novartis's Zometa® prior to the expiration of U.S. Patent Nos. 7,932,241 ("the '241 patent") and 8,324,189 ("the '189 patent").

THE PARTIES

A. Novartis

3. Plaintiff Novartis is a corporation organized under Delaware law. Its principal place of business is in East Hanover, New Jersey. Novartis owns the '241 and '189 patents.

B. The Generic Defendant: Akorn, Inc.

4. Akorn, Inc. is a corporation organized under Louisiana law. Its principal place of business is in Lake Forest, Illinois.

5. Upon information and belief, Akorn Ophthalmics, Inc. is a wholly-owned subsidiary of Akorn, Inc. Akorn Ophthalmics, Inc. is a corporation organized and existing under the laws of New Jersey, having its principal place of business in Somerset, NJ. Akorn, Inc. has availed itself of the legal protections of the State of New Jersey by, among other things, creating a subsidiary with its principal place of business in New Jersey (*i.e.*, Akorn Ophthalmics, Inc.).

6. Upon information and belief, Akorn, Inc., is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for distribution in the United States, including in this judicial district.

7. Upon information and belief, Akorn, Inc. submitted to the FDA ANDA No. 204935 seeking approval to a market generic version of Zometa.

JURISDICTION AND VENUE

8. This action seeks to enforce federal patent rights under federal law. Accordingly, this Court has federal question jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and declaratory judgment jurisdiction under 28 U.S.C. §§ 2201 and 2202.

9. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

10. This Court has personal jurisdiction over the defendant for the following reasons, among others:

a) The defendant has sold generic drugs in New Jersey, and is seeking approval to sell and/or distribute generic versions of Zometa in New Jersey;

b) Novartis, which will be harmed by the defendant's actions, is domiciled in New Jersey; and

c) Defendant Akorn has systematic and continuous contacts with New Jersey, in that, among other things, it sells, manufactures, imports and/or distributes generic drugs in New Jersey.

STATEMENT OF FACTS

A. Novartis's Branded Products

11. The active ingredient in Zometa is zoledronic acid. Zometa was first approved by the FDA in 2001 and is approved to treat hypercalcemia of malignancy (HCM), a condition resulting

in high calcium blood levels due to cancer, multiple myeloma and bone metastases from solid tumors. Zometa's primary indication is for the prevention of skeletal-related complications associated with cancer, such as fractures and pain.

12. Zometa is administered intravenously as a 4 mg dose of zoledronic acid diluted in standard buffer media. Zometa has been sold in three forms: (a) a "pre-concentrate" vial of 4 mg of Zometa diluted in 5 mg of buffer, which must be further diluted before administration to a patient; (b) a "Ready to Use" or "RTU" vial of 4 mg of Zometa in fully diluted form; and (c) a 4 mg vial of powder, which would be diluted by an infusion center before administration to a patient (this product was discontinued in 2003). Unopened, Zometa has a shelf life of three years.

B. The Patents-In-Suit

13. The '241 patent, entitled "Pharmaceutical products comprising bisphosphonates," was duly and legally issued on April 26, 2011 and is owned by Novartis. A copy of the '241 patent is attached as Exhibit A.

14. The '189 patent, entitled "Use of zolendronate for the manufacture of a medicament for the treatment of bone metabolism diseases," was duly and legally issued on December 4, 2012, and is owned by Novartis. A copy of the '189 patent is attached as Exhibit B.

15. Zometa and its methods of use are covered by one or more claims of the '241 and '189 patents, which have been listed in connection with Zometa in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is also referred to as the "Orange Book." Accordingly, the defendant has actual or constructive knowledge of each of the patents.

C. The ANDA Process

16. The FDA regulates the manufacture, sale and labeling of prescription drugs in the U.S. Under the 1984 Hatch-Waxman Act, companies wishing to bring a generic version of a branded prescription drug to market can submit an Abbreviated New Drug Application (ANDA) to the FDA. 21 U.S.C. § 355(j). This ANDA process allows the generic drug maker to avoid the expensive clinical trials required of an NDA holder to demonstrate a drug's safety and effectiveness. The generic company simply relies on the original NDA submission for that purpose.

17. The Hatch-Waxman Act also contains provisions meant to balance the interests of branded and generic companies in resolving claims concerning the branded company's patents. The Act requires drug makers to identify the patents covering their drugs in the Orange Book. 21 U.S.C. § 355(b)(1)(c)(2). When seeking ANDA approval, the applicant must take certain actions with respect to listed patents.

18. Under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), an applicant can assert that the branded drug's Orange Book patent(s) is/are invalid, unenforceable, and/or will not be infringed, a so-called "Paragraph IV certification." Such a certification is provided to the FDA and notice is given to the NDA holder and patent owner. Upon receiving notice of the certification, the NDA holder or patent owner can choose to enforce its patents in federal court.

D. The Generic's ANDA Application

19. As noted above, Defendant Akorn has submitted an ANDA seeking approval to manufacture and sell generic versions of Zometa.

20. Defendant Akorn notified Novartis by letter that it had submitted to the FDA ANDA No. 204935 for a generic version of Zometa.

21. With respect to ANDA No. 204935, which seeks approval to market a generic version of Zometa, Defendant Akorn stated that its ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) with respect to the ’241 and ’189 patents, alleging that they are invalid and/or will not be infringed by the commercial manufacture, use, offer for sale or sale of the Defendant Akorn’s generic Zometa products.

COUNT I (INFRINGEMENT OF THE ‘241 PATENT)

22. Each of the preceding paragraphs 1 to 22 is incorporated as if fully set forth herein.

23. Defendant Akorn’s generic Zometa products are covered by one or more claims of the ’241 patent.

24. Defendant Akorn’s submission of ANDA Nos. 204935, for the purposes of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of its generic Zometa products before the expiration of the ’241 patent is an act of infringement of the ’241 patent.

25. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendant Akorn’s generic Zometa products would infringe one or more claims of the ’241 patent.

26. Upon information and belief, Defendant Akorn intends to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its generic Zometa products immediately and imminently upon approval of Akorn’s ANDA No. 204935.

27. There is an actual and justiciable case or controversy between Novartis and Defendant Akorn concerning the validity and infringement of the ‘241 patent. Novartis is entitled to a declaration that Defendant Akorn’s commercial manufacture, use, sale, offer for sale, and/or importation of their generic Zometa drug products will infringe one or more claims of the ‘241 patent and that the claims of the ‘241 patent are not invalid.

28. Unless Defendant Akorn is enjoined from infringing the ’241 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT II (INFRINGEMENT OF THE ‘189 PATENT)

29. Each of the preceding paragraphs 1 to 29 is incorporated as if fully set forth herein.

30. The use of Defendant Akorn’s generic Zometa products is covered by one or more claims of the ’189 patent.

31. Upon information and belief, Defendant Akorn knew of the ’189 patent when it submitted ANDA No. 204935, and know or are willfully blind to the fact that their actions will induce or contribute to direct infringement of the ’189 patent.

32. Defendant Akorn’s submission of ANDA No. 204935, for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of its Zometa products before the expiration of the ’189 patent is an act of infringement of the ’189 patent under 35 U.S.C. § 271(e)(2).

33. Use of Defendant Akorn’s generic Zometa products in accordance with and as directed by Defendant Akorn’s proposed labeling for those products would infringe one or more claims of the ’189 patent.

34. Upon information and belief, Defendant Akorn intends to engage in the manufacture, use, offer for sale, sale, and/or importation of its generic Zometa products with its proposed labeling immediately and imminently upon approval of its ANDA.

35. Upon information and belief, Defendant Akorn will actively induce infringement of the ‘189 patent in violation of 35 U.S.C. § 271(b) when its ANDA is approved, and plans and intends to, and will do so immediately and imminently upon approval.

36. Upon information and belief, Defendant Akorn knows that its generic Zometa products

and its proposed labeling are especially made or adapted for use in infringing the '189 patent, and that its generic Zometa products and its proposed labeling is not suitable for substantial noninfringing use.

37. Upon information and belief, Defendants Akorn plan and intend to, and will, contribute to the infringement of the '189 patent immediately and imminently upon approval of its generic Zometa products in violation of 35 U.S.C. § 271(c).

38. There is an actual and justiciable case or controversy between Novartis and Defendant Akorn concerning the validity and infringement of the '189 patent. Novartis is entitled to a declaration that Defendant Akorn's manufacture, use, sale, offer for sale, and/or importation of its generic Zometa drug products will infringe, contribute to the infringement of and/or actively induce the infringement of one or more claims of the '189 patent, and that the claims of the '189 patent are not invalid.

39. Unless Defendant Akorn is enjoined from infringing the '189 patent, actively inducing infringement of the '189 patent, and/or contributing to the infringement by others of the '189 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis requests entry of judgment in its favor and against defendant as follows:

1. Declaring that the '241 and '189 patents are not invalid;

2. Declaring that the Defendant has infringed, directly or indirectly, one or more claims of the '241 and '189 patents;

3. Damages or other monetary relief to Novartis if defendant engages or continues to engage in commercial manufacture, use, offers to sell, sale, or importation into the United States

of generic versions of Zometa prior to the latest expiration date of the ’24l and/or ’189 patents, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

4. Declaring that the Defendant by engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States of generic versions of Zometa have willfully infringed the claims of the ’241 and/or ’189 patents;

5. An order permanently enjoining Defendant, and its affiliates, subsidiaries, officers, agents, servants and employees and those acting in privity or in concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States generic versions of Zometa until after the latest expiration date of the patent relating to approved presentations, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled; and

6. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: November 8, 2013

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I certify that to the best of my knowledge, the matter in controversy is the subject of:

- *Novartis Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA (consolidated) filed on June 27, 2012 in the District of New Jersey.

- *Novartis Pharmaceuticals Corporation et al. v. Akorn et al.*, Civil Action No. 2:13-cv-05125-SDW-MCA filed on August 26, 2013 in the District of New Jersey.

Dated: November 8, 2013

Respectfully Submitted,

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